

In the specification:

Replace the present application title with the amended title set forth below.

THERAPY FOR FUNCTIONAL DYSPEPSIA

Replace the paragraph on page 1, lines 23-31 with the amended paragraph below.

There are a few reports in the literature of animal models for the use in studying pressure-volume handling in conscious animals. Bueno *et al* disclosed a rat model to study gastric sensitivity and measured the maximal volume at a pressure of 20 mmHg and the visceromotor response related to maximal volume (*Neurogastroenterology & Motility*, 10(2):157-63, 1998). Paterson *et al* conducted studies in dogs using barostat technique and examined the effect of different pharmacological substances on the maximum volume of the stomach (*Neurogastroenterology & Motility*, 12(4):301-6, 2000). No studies ~~has~~ have been reported where the physico-mechanical properties of the stomach ~~has~~ have been studied in detail in response to distension.

Replace the paragraph on page 3, lines 1-16 with the amended paragraph below.

In another aspect, the invention features a method of diagnosing functional dyspepsia in a human. The method includes inserting a balloon into the stomach of a test human suspected of having functional dyspepsia; applying a start minimum pressure to the balloon such that the stomach of the test patient is not distended and determining the volume response; increasing the pressure in the balloon to a maximum pressure of not more than 20 mmHg, such that the stomach is distended and determining the volume response; maintaining the distension pressure in the stomach for a specified period of time until a maximum volume is reached and determining the volume response; lowering the pressure in the balloon to the start minimum pressure and measuring the volume response; and comparing the volume response of the test human and a control human not having functional dyspepsia, wherein a reduction in the maximum gastric accommodation capacity of the test human compared to the maximum gastric accommodation capacity of the control human is indicative that the test human has functional dyspepsia. In one embodiment, the start minimum pressure is 1 mmHg. In another embodiment, the maximum pressure is 12 mmHg. In yet another embodiment the maintained ~~distention~~ distension pressure is 12 mmHg.

Replace the paragraph running from page 4, line 29 through page 5, line 8 with the amended paragraph set forth below.

FD is a chronic, ~~recurrent~~ recurrent, often meal-related epigastric disorder. It is a disorder of unknown aetiology and ~~diagnoses~~ diagnosis is often made by the pattern of symptoms presented by an FD patient. Symptoms include nausea, vomiting, bloating, early satiety and epigastric pain. At present, doctors prescribe a large number of different agents alone, or in combination, to treat FD. Because there is no objective parameter for determining the efficacy of an agent, the only means to assess a drug's efficacy is to determine its effects on relieving the symptoms in the patient. Examples of drugs used to treat FD include ~~antiacids~~ antacids, antisecretory agents, prokinetics, mucosal protective agents, bismuth, ~~anticholinergics~~ anticholinergics, alginates, anti-foams, peppermint oil, herbal medication, tranquillisers\antidepressants or antibiotics. However, none of these drugs provide efficient treatment.

Replace the paragraph running from page 7, line 26 through page 8, line 5 with the amended paragraph set forth below.

While not wishing to be bound by theory, applicants believe that the physiological explanation for why during the Tonic phase the volume in the stomach increases despite the fact that the pressure is constant may be because the stomach continues relaxing during this tonic phase. In order for the barostat to keep the pressure constant it needs to pump more air into the stomach. The total volume change during the tonic phase thus

represents the adaptive accommodation of the stomach and the slope of this increase (U) represents the maximum gastric accommodation capacity of the stomach. The results obtained using the distension protocol outlined herein show that the maximum gastric adaptive accommodation ~~are~~ is significantly lower in WKY rats and Functional dyspeptic patients compared to Sprague Dawley rats, and persons not diagnosed FD, respectively. Even more interestingly, our studies have shown that the pressure volume curves of the WKY rats and Functional dyspeptic patients are very similar (see Figure 4a & 4b).

Replace the paragraph on page 9, lines 9 and 10 with the amended paragraph set forth below.

The ~~accompanied~~ accompanying Figures and the following Examples support and illustrate the claimed invention.

Replace the paragraph on page 9, lines 14 and 15 with the amended paragraph below.

The aim of the present study was to determine if a distension model in a rat stomach had similar physico-mechanical properties ~~as the~~ to those of the stomach of a patient with FD.

Replace the paragraph on page 13, lines 5-8 with the amended paragraph set forth below.

During the first phase of the curve the pressure in the stomach is constant (1 mmHg) and the barostat will not pump in any air into the stomach, that is if the stomach ~~dese~~ does not relax. During this period the amount of air pumped into or drawn out of the stomach is solely dependent on the relaxation or contraction of the stomach.

Replace the paragraph on page 13, lines 10-13 with the amended paragraph set forth below.

During the ramp phase the barostat will infuse air into the stomach even if the stomach ~~dese~~ does not relax until the preset pressure is reached. The volume pumped during this period is dependent on the activity of the barostat, which wants to increase the pressure and the relaxation or contraction of the stomach.

Replace the paragraph on page 13, lines 20-31 with the amended paragraph set forth below.

At the beginning of the ramp period when the barostat starts increasing the pressure in the stomach the velocity of the infused pump is dependent on, among other things, the elasticity of the stomach. That is, the more ~~compliant~~ compliant the stomach is the larger amount of air will be needed to increase the pressure to a constant level. This property of the stomach can be seen in the deflection point of the volume curve. As the pressure and/or volume increase it reaches a level where the stomach starts relaxing. The barostat, then, in order to be able

to increase the pressure linearly as preset, will increase the velocity of the influent air into the stomach as can be seen in the change in the velocity (slope) of the second part of the volume curve. It must be mentioned that even though in this context we refer to the deflection point as "a point" it ~~does~~ does not mean that in reality it is a single point where the relaxation starts. This point is merely a reflection of a measurable point of the start of the relaxation of the stomach.

Replace the paragraph on page 14, lines 10-19 with the amended paragraph set forth below.

During the Tonic phase the volume in the stomach increases despite the fact that the pressure is constant (Passive barostat period). The only explanation for this is that the stomach continues relaxing during this tonic phase and in order for the barostat to keep the pressure constant it needs to pump more air into the stomach. This is true if the system ~~does~~ does not leak. This aspect is checked always before and after each experiment and a very good indicator that leakage is not the reason for the increase in the volume of the stomach during the tonic phase is the fact that the volume always reaches a maximum and plateaus at that volume. The total volume change during the tonic phase (K) represents the adaptive accommodation of the stomach and the slope of this increase (U) represents the maximum gastric accommodation capacity.

Replace the paragraph on 14, lines 21-24 with the amended paragraph set forth below.

When the pressure drops to the minimum distension pressure of 1mmHg after the tonic phase the gastric volume ~~de~~ does not decrease to its value before the distension. The volume decreases to a level dictated by the elasticity of the stomach. The value (R), then, ~~can then~~ represents the elasticity of the stomach.